REMARKS

Claims 14-23 and 26-29 are under examination. Applicants hereby amend claims 14, 19, and 26 without conceding to the Examiner's rejections and without prejudice. Claims 24 and 25 have been canceled without prejudice.

35 U.S.C. § 112

The Examiner rejected claim 24 because it recites "one phase" for which phrase the Examiner failed to find support. Thus, the Examiner found that Claim 24 fails "to comply with the written description requirement." Applicants, without conceding this argument, have canceled claim 24 and amended claims 14 and 19 to read "wherein the composition is a single composition." Support for this amendment is found in the entire specification but especially in the Examples wherein the preparation of each example is described as having "the following composition;" i.e., a single composition. Applicants are clearly in possession of the claimed invention and the Examiner is requested to remove this rejection.

35 U.S.C. § § 102 or 103

Claims 14-29 are rejected as being anticipated by or as being obvious over Saint-Leger (U.S. 5,650, 145) (hereafter "Saint-Leger"). Applicants traverse this rejection.

Saint-Leger

Applicants have amended the claims to be limited to "an active component consisting of" the claimed 1-hydroxy-2-pyridone. Saint-Leger teaches the use of two

active components (an antifungal agent and antibacterial agent) (as noted by the Examiner on p. 5 of the Office action). Since Applicants' invention includes only one active component, an antifungal agent (the claimed 1-hydroxy-2-pyridone), Saint-Leger, which requires two active components, cannot anticipate the claims. As Saint-Leger does not teach every element of the claimed invention, Applicants respectfully request that the §102 rejection be removed.

Additionally, the Examiner asserts that Saint-Leger's Example 1 is identical to Applicants' invention save for the pH limitations, which would be "an obvious modification of" Example 1. Applicants traverse this rejection. In order to establish obviousness, the prior art must teach all of the elements of the claim. Applicants' claims have been amended to have only the claimed 1-hydroxy-2-pyridone as the active component. Saint-Leger requires (even in Example 1) an additional active component, an antibacterial agent (e.g., Triclosan; *see* Saint-Leger, Col. 4, lines 9-10). Therefore, all of the elements of Applicants' claims are not taught in the cited art and Applicants respectfully assert the rejection should be removed.

Further, the references themselves must contain a teaching or suggestion of the modifications necessary to read on the claimed invention. The Examiner notes that Saint-Leger "describes a method for treating a male human patient with a composition applied to the scalp, resulting in a change in seborrhea." Saint-Leger teaches only reduction of and treatment of hair loss and some modification of seborrhea. Nothing in Saint-Leger teaches or suggests a modification to treat seborrheic dermatitis. All of the pending claims cover the method of treating seborrheic dermatitis, not hair loss or seborrhea unrelated to seborrheic dermatitis. While seborrheic dermatitis may occur on

oily-looking skin (seborrhea oleosa), seborrhea is not always present in seborrheic dermatitis patients. Sebaceous gland activity increases (producing seborrhea) in childhood and puberty but decreases in adulthood, while seborrheic dermatitis often occurs in adulthood. *See* Fitzpatrick's Dermatology in General Medicine, Vol. I, 6th ed., p. 1198 (attached as Exhibit A). Therefore, even though Saint-Leger describes a change in seborrhea, that does not equate with treatment of seborrheic dermatitis, and there is no suggestion or teaching of any such modification in Saint-Leger. Applicants respectfully request that this § 103 rejection be removed.

Saint-Leger and Lange

The Examiner rejects claim 19 as obvious over Saint-Leger and Lange. Applicants traverse this rejection. Applicants have amended the claims to be limited to compositions with only a specific anti-fungal agent (a 1-hydroxy-2-pyridone) as the active component, and that the composition is a single composition.

Saint-Leger, as set forth above, requires an antibacterial and an antifungal agent in the same composition, and therefore does not teach all of the elements of the claim. There is no suggestion or teaching to modify Saint-Leger to use only one active component. Even in combination with Lange, there is no such suggestion or teaching. Lange teaches a "two phase" composition meaning, in effect, that there are two different compositions which are not compatible, are packaged separately, and must be applied sequentially. (*See* Col. 2, lines 5-12, Col. 6, lines 39-57). The compositions must be used in the particular order described in the patent or the benefits of Lange will not be achieved. (Col. 2, lines 13-20). Therefore, Lange teaches away from Applicants'

invention of a single composition with only one antifungal agent as its active component. Applicants respectfully request the removal of this § 103 rejection.

Provisional Double Patenting

Applicants note that the Examiner has maintained the provisional double patenting rejection over the claims of co-pending Application No. 09/077,194. In the event that the '194 Application issues as a patent, Applicants will provide a terminal disclaimer.

CONCLUSION

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 14-23 and 26-29 in condition for allowance. Applicants submit that the proposed amendments of claims 14, 19, and 26 do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner, since all of the elements and their relationships claimed were either earlier claimed or inherent in the claims as examined. Therefore, this Amendment should allow for immediate action by the Examiner.

Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

In view of the foregoing remarks, Applicants submit that this claimed invention, as amended, is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this

Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Finally, should any outstanding issues remain, Applicants respectfully submit a request for a personal interview with the Examiner.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 11, 2005

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Attachments: Exhibit A - Fitzpatrick's Dermatology in General Medicine, Vol. I, 6th ed., p. 1198.

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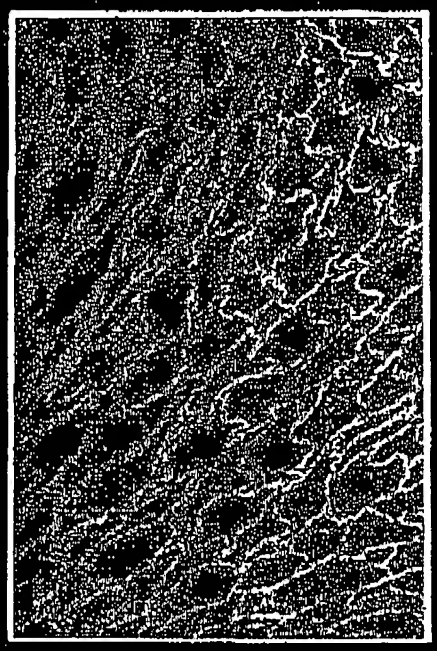
Fitzpatrick's DERMATOLOGY in GENERAL MEDICINE



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CHAPTER 124

Gerd Plewig
Thomas Jansen

Seborrheic Dermatitis

Seborrheic dermatitis is a common chronic papulosquamous dermatosis that is usually easily recognized. It affects infants and adults and is often associated with increased sebum production (seborrhea) of the scalp and the sebaceous follicle-rich areas of the face and trunk. The affected skin is pink, edematous, and covered with yellow-brown scales and crusts. The disease varies from mild to severe, including psoriasiform or pityriasiform patterns and erythroderma.[1] Seborrheic dermatitis is one of the most common skin manifestations in patients with human immunodeficiency virus (HIV) infection.[2] Consequently, it is included in the spectrum of premonitory lesions and should be carefully evaluated in high-risk patients.

INCIDENCE

Seborrheic dermatitis has two age peaks, one in infancy within the first 3 months of life and the second around the fourth to the seventh decades of life. No data are available on the exact incidence of seborrheic dermatitis in infants, but the disorder is common. The disease in adults is believed to be more common than psoriasis, for example, affecting at least 3 to 5 percent of the population in the United States.[3] Men are affected more often than women in all age groups. There does not appear to be any racial predilection. Seborrheic dermatitis is found in up to 85 percent of patients with HIV infection.[2]

ETIOLOGY AND PATHOGENESIS

Although many theories abound, the cause of seborrheic dermatitis remains unknown.

Seborrhea

The disease is associated with oily-looking skin (seborrhea oleosa), although an increased sebum production cannot always be detected in these patients.[4] Even if seborrhea does provide a predisposition, seborrheic dermatitis is not a disease of the sebaceous glands. The high incidence of seborrheic dermatitis in newborns parallels the size and activity of the sebaceous glands at this age. It has been shown that newborns have large sebaceous glands with high sebum secretion rates similar to adults.[5] In childhood, sebum production and seborrheic dermatitis are closely connected. In adulthood, however, they are not, as the sebaceous gland activity peaks in early puberty and decades later seborrheic dermatitis may occur.

The sites of predilection—face, ears, scalp, and upper part of the trunk—are particularly rich in sebaceous follicles. Two diseases are prevalent in these regions: seborrheic dermatitis and acne. In patients with seborrheic dermatitis, the sebaceous glands are often particularly large on cross-sectional histologic specimens. In one study, skin surface lipids were not elevated but the lipid composition was characterized by an increased proportion of cholesterol, triglycerides, and paraffin, and a decrease in squalene, free fatty acids, and wax esters.[6] However, mild abnormalities in the skin surface lipids could well result from the ineffective keratinization, which is often demonstrable histopathologically. Seborrheic dermatitis seems to be more frequent in patients with parkinsonism, in whom sebum secretion is increased. Similarly, after reduction of sebum production induced by levodopa and by promestriene, seborrheic dermatitis may improve.

The synonym *eczéma flannelaire* stems from the idea that a retention of skin surface lipids by clothing and rubbing of the rough textiles on the skin—cotton (flannel), wool, or synthetic underwear in particular—promotes or aggravates seborrheic dermatitis.

Microbial Effects

Unna and Sabouraud, who were among the first to describe the disease, favored an etiology involving bacteria, yeasts, or both. This hypothesis has remained unsupported, although bacteria and yeast can be isolated in great quantities from affected skin sites.

In infancy, *Candida albicans* is often found in dermatitic skin lesions and in stool specimens. Although intracutaneous tests with candidin, positive agglutinating antibodies in serum, and positive lymphocyte-transformation tests in affected infants revealed sensitization to *C. albicans*, these observations cannot be convincingly linked to the pathogenesis.

Aerobic bacteria were recovered from the scalp of patients with seborrheic dermatitis (140,000 bacteria/cm^2 versus 280,000 in normal individuals and 250,000 in persons with dandruff). In contrast, *Staphylococcus aureus* was rarely seen in normal persons or those with dandruff. *Staphylococcus* was recovered in about 20 percent of patients with seborrheic dermatitis, accounting for an average of about 32 percent of the total skin flora.[7]

Propionibacterium acnes counts were low in patients with seborrheic dermatitis (7550 bacteria/cm^2 in those without dandruff). The small quantities of *P. acnes* in patients with seborrheic dermatitis may explain the low yield of free fatty acids from their skin surfaces.

The lipophilic yeast *Pityrosporum* is abundant in normal skin (504,000 organisms/cm^2 versus 922,000 in individuals with dandruff and 665,000 in patients with seborrheic dermatitis).[7] This organism has received particular attention in recent years. Some authors claim strong evidence in favor of a pathogenic role for these microbes, whereas others do not share this view. Their argument is that *Pityrosporum ovale* is not the causative organism, but is merely present in large numbers. In patients with pityriasis versicolor[8] and *Pityrosporum* folliculitis,[9] seborrheic dermatitis has been found in a higher percentage than expected. Clearing of seborrheic dermatitis by selenium sulfide and continued suppression of *P. ovale* with topical amphotericin B caused a